

We claim:

1. A method for manufacturing an endovascular graft, or section thereof, comprising:

5 a. disposing a first layer of fusible material onto a shape forming member;

b. disposing a second layer of fusible material onto at least a portion of the first layer forming an overlapped portion of the first and second layers of fusible material;

10 c. forming a seam in the layers of fusible material to form at least one inflatable channel in the overlapped portion of the first and second layers of fusible material;

d. expanding the inflatable channel; and

15 e. fixing the fusible material that forms the channel while the channel is in an expanded state.

2. The method of claim 1 further comprising disposing adhesive or melt-processible material on the first layer of fusible material prior to disposing the second layer of fusible material.

20 3. The method of claim 2 wherein the adhesive or melt-processible material is selected from the group comprising perfluoroalkoxy and fluorinated ethylene propylene.

4. The method of claim 1 wherein the fusible material forming the inflatable channel is fixed by sintering.

5. The method of claim 4 wherein the sintering process comprises bringing the material of the inflatable channel to a temperature of about 335 to about 380 degrees Celsius.

6. The method of claim 1 wherein third, fourth, fifth, and sixth additional layers of fusible material are disposed on the shape forming member after the step of disposing the second layer, and the seam is created in the layers such that the inflatable channel is formed by the seam between the third and fourth layers.

7. The method of claim 1 wherein the fusible material comprises ePTFE.

8. The method of claim 1 wherein the shape forming member comprises a cylindrically shaped member and the overlapped portion comprises a substantially tubular member.

9. A method for manufacturing an endovascular graft, or section thereof, comprising the steps of:

a. forming an overlapped portion of a first layer of fusible material and at least one additional layer of fusible material;

c. forming at least one inflatable channel in the overlapped portion of the layers of fusible material;

d. expanding the inflatable channel; and

e. fixing the fusible material that forms the channel while the channel is in an expanded state.

10. A method for manufacturing an endovascular graft, or section thereof, comprising:

a. disposing a first layer of fusible material onto a shape forming member;

b. positioning at least one expandable member onto the first layer of fusible material;

c. disposing at least one additional layer of fusible material over the first layer of fusible material and at least a portion of the expandable member;

d. forming a seam between the first and at least one additional layer of fusible material adjacent the expandable member to secure the expandable member to the first and at least one additional layer;

e. selectively forming a seam in the layers of fusible material to form at least one inflatable channel in the first and at least one additional layers of fusible material; and

f. expanding the inflatable channel and fixing the material that forms the inflatable channel when the channel is in an expanded state.

11. The method of claim 10 further comprising disposing a melt-processible or adhesive material on or adjacent the expandable member and first layer of fusible material prior to placing the additional layer of fusible material onto the first layer.

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12. The method of claim 11 wherein the adhesive material is selected from the group comprising perfluoroalkoxy and fluorinated ethylene propylene.

13. The method of claim 10 wherein the expandable member comprises an expandable stent.

5 14. The method of claim 10 wherein the expandable member comprises an expandable connector ring configured to be secured to an expandable stent.

15. The method of claim 10 wherein injection of pressurized fluid into the inflatable channel is used to expand the inflatable channel.

10 16. The method of claim 15 wherein a mold is used to constrain the fusible material during expansion of the inflatable channel.

17. The method of claim 10 wherein the fusible material of the inflatable channel is fixed by sintering while the inflatable channel is in an expanded state.

18. A method for manufacturing an endovascular graft, or section thereof, comprising the steps of:

15 a. positioning at least one expandable member between the layers of an overlapped portion of a first layer of fusible material and a second layer of fusible material;

b. forming a seam adjacent the expandable member so to mechanically capture the member within the first and second layers of fusible material;

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e. forming at least one inflatable channel in the overlapped portion of the first and second layers of fusible material; and

f. expanding the inflatable channel and fixing the material forming the inflatable channel while the channel is in an expanded state.

19. A method for manufacturing an endovascular graft, or section thereof, comprising:

5 a. disposing a first layer of fusible material and at least one additional layer of fusible material onto a shape forming member such that at least a portion of the first and second layers is overlapped, forming an overlapped portion;

b. selectively fusing the layers of fusible material together in a seam to form at least one inflatable channel in the overlapped portion of the first and additional layers of fusible material.

20. The method of claim 19 further comprising forming a plurality of inflatable channels between the first and second layers of fusible material.

15 21. The method of claim 20 wherein the plurality of channels are all in fluid communication.

22. The method of claim 19 wherein the fusible material comprises ePTFE.

20 23. The method of claim 19 wherein the inflatable channel is formed between the first and additional layers of fusible material by the application of heat and pressure.

24. The method of claim 23 wherein the application of heat and pressure is carried out with a heated stylus that is pressed against and translated relative to the overlapped portions.

25. The method of claim 24 wherein the movement of the heated stylus relative to the overlapped portion is automatically controlled.

26. The method of claim 25 wherein the movement of the heated stylus relative to the overlapped portion may comprise up to five axes of movement.

27. The method of claim 24 wherein the temperature of the heated stylus tip is from about 350 to about 525 degrees Celsius.

28. The method of claim 24 wherein the pressure applied to the layers in forming the seam is from about 300 to about 3,000 psi.

29. The method of claim 19 wherein the shape forming member comprises a cylindrical mandrel and wherein the first layer and the at least one additional layer of fusible material are disposed onto the mandrel by wrapping the layers thereabouts.

30. The method of claim 19 wherein the shape forming member comprises a mandrel, wherein the first layer and the at least one additional layer of fusible material are disposed onto the mandrel by wrapping the layers thereabout, and wherein the mandrel comprises a first end section, a second end section and a middle section disposed between the first end section, the middle section having transverse dimension less than a transverse dimension of the first or second end sections.

31. The method of claim 19 wherein at least two seams are formed between the at least two layers of fusible material to form at least one inflatable channel disposed between layers of fusible material.

32. The method of claim 31 wherein the inflatable channel is expanded  
5 by internal pressure after being formed.

33. The method of claim 32 wherein a pressure line configured to deliver fluid is inserted between the first and second layers of fusible material.

34. The method of claim 33 wherein the pressure line comprises a tubular member configured to be disposed between the first and second layers of  
10 fusible material, the tubular member comprising a plurality of apertures whose cross sections increase in size distally along the tubular member.

35. The method of claim 32 further comprising sintering the endovascular graft while the at least one inflatable channel is in an expanded state.

15 36. The method of claim 35 wherein the at least one inflatable channel is expanded into a mold while being sintered.

37. A method for manufacturing an endovascular graft, or section thereof, comprising the steps of:

20 a. forming an overlapped portion of at least two layers of fusible material; and

b. forming at least one inflatable channel in the overlapped portion.

38. A seam forming apparatus configured to create one or more seams between overlapped layers of fusible material of an endovascular graft section, comprising:

a. a stylus;

b. a mount system moveable relative to the stylus in a controllable pattern;

c. at least one motor coupled to the mount system and controllable by a preprogrammed database that moves the mount system relative to the stylus in a predetermined pattern.

39. The device of claim 38 wherein the stylus is spring-loaded in a lateral direction.

40. The device of claim 38 wherein the stylus is spring-loaded in an axial direction.

41. The device of claim 38 wherein the stylus is configured to operate at a temperature of about 330 to about 525 degrees Celsius.

42. The device of claim 38 wherein the stylus pivots about a pivot axis under spring-loaded tension.

43. The device of claim 42 wherein the spring-loaded force at the distal extremity of the stylus is about 0.5 to about 100 grams.

44. The device of claim 38 comprising at least five motors controlled by a preprogrammed database using computer numerical control which are configured



to move the mount system relative to the stylus in a different degree of freedom for each motor.

45. The device of claim 38 further comprising a mandrel secured to the mount system which supports the overlapped portion of the layers of fusible material and provides a substrate to oppose the force of the stylus tip.

46. The device of claim 38 wherein the predetermined pattern for seam formation includes an inflatable channel network in a graft body portion of the endovascular graft, or section thereof.

47. The device of claim 38 wherein the predetermined pattern for seam formation includes at least one circumferential inflatable channel in a graft body portion of the endovascular graft, or section thereof.

48. A seam forming apparatus configured to create one or more seams between overlapped layers of fusible material of an endovascular graft section, comprising:

a. means for forming a seam between the layers of fusible material;

b. a mount means moveable relative to the means for forming a seam in a controllable pattern; and

c. at least one motor means connected to the mount means which is controllable by a preprogrammed database and for moving the mount system relative to the heated stylus in a predetermined pattern.

49. A three piece mandrel used as a shape forming member for manufacture of an endovascular graft, or section thereof, comprising:

a middle section that is substantially circular or elliptical a transverse cross section;

5 a first end section that is substantially elliptical or circular in a transverse cross section, with at least a portion that is larger in a transverse dimension than the middle section and that is removably secured to a first end of the middle section; and

10 a second end section that is substantially elliptical or circular in transverse cross section, with at least a portion that is larger in a transverse dimension than the middle section and which that is removably secured to a second end of the middle section.